

Appln. No. 09/833,017  
Amendment

### REMARKS/ARGUMENT

In the Office Action of July 16, 2003, certain claims stand rejected under 35 U.S.C. § 112, first paragraph; certain claims are rejected under 35 U.S.C. § 112, second paragraph; and all claims are rejected under 35 U.S.C. § 102(b) as anticipated by *Russell*.

#### Examiner Interview Summary

Applicants gratefully acknowledge the interview with Examiner Baskar on November 24, 2003. The claims, suggested amendments, and the Russell reference were discussed. Applicants indicated that a set of proposed claim amendments in line with the Examiner's suggestions and Applicant's proposals would be provided. It was agreed that some of the proposed amendments should separate and focus the issues with respect to SEQ ID NO. 2 or SEQ ID NO. 4. The Examiner indicated that clarification of the current PTO policy and guidelines would be obtained regarding claims for "% sequence identify" and "fragments" with respect to the 46 amino acid sequence (SEQ ID NO:2) and its 21 amino acid fragment (SEQ ID NO:4), having the specified CSP activity.

Applicants submit herewith claim amendments that are believed to be consistent with the discussion that took place in the Examiner Interview. With respect to currently amended claim 25, there is support at paragraphs 53, 54, 56 and 60; the screening assays in paragraphs 78 and 80; knowledge and skill in the art; and example 14 of the synopsis of application of the written description guidelines. The assay disclosed in paragraph 78 is an assay of genetic competence. this is one way to determine if a polypeptide has *S. mutans* competence signal peptide activity. The assay disclosed in paragraph 80 is an assay of acid resistance tolerance. This is another way to determine if a polypeptide has *s. mutans* competence signal peptide activity. The last sentence of each paragraph indicates how these assays might be applied to screen for inhibitors of CSP. Paragraphs 82 and 83 are also directed to methods of screening for inhibitors of CSP activity. New claim 60 is similar in that it relates to SEQ ID NO. 4.

Claim 27 is currently amended to recite that SEQ ID NO. 4 (21 AAs) has 45% sequence identity to seq id no: 2 (46 AAs), and possesses CSP activity. Percent sequence identity is calculated as  $46 - 25 = 21$  and  $21/46 = \text{about } 45\%$ . Support is at paragraphs 53, 54, 56, 60; the screening assays in paragraphs 78 and 80; knowledge and skill in the art; example 14 of the synopsis of application of the written description guidelines. The SEQ ID NO. 4 limitation has been deleted and reintroduced as new claim 61 in order to separate the issues relating to % identity to SEQ ID NO. 2 or 4.

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Claim 38 is currently amended to depend from claim 58 instead of claim 24 and recites "having *S. mutans* competence signal peptide activity." Reference to SEQ ID NO. 4 has been moved to new claim 62 in order to focus the separate issues of SEQ ID NO. 2 and SEQ ID NO. 4 deletions. Note that SEQ ID NO. 4 is an example of removing 25 AAs from one end of SEQ ID NO. 2 to get an active CSP peptide. Support for claims 38-41 and new claims 62-66 is at paragraphs 52-54. Assay protocols for screening the shortened sequences is in paragraphs 74, 78, 80, 89.

Claim 39 is currently amended to delete reference to SEQ ID NO. 4, and new claim 63 is like claim 39 except that it refers to SEQ ID NO. 4.

Similarly, currently amended claim 39 delete reference to SEQ ID NO. 4, and new claim 64 is like claim 40 except that it refers to SEQ ID NO. 4.

Currently amended claim 41 omits reference to SEQ ID NO. 4, and new claim 65 is introduced to recite the same limitations as claim 41, except that it refers to only SEQ ID NO. 4.

Claim 42 is currently amended to omit reference to SEQ ID NO. 16. SEQ ID NO. 16 is the same as SEQ ID NO. 4 except it refers to the synthetically made product. This amendment obviates the new matter objection.

In currently amended claim 43 SEQ ID NO. 4 has been removed to new claim 66 in order to focus the separate issues of SEQ ID NO. 2 and SEQ ID NO. 4 modifications. Support for this claim is at paragraphs 53, 54 and 56; the screening assays in paragraphs 78 and 80; knowledge and skill in the art; and example 14 of the synopsis of application of the written description guidelines.

Claims 45 and 46, as currently amended, find support as discussed above with respect to claim 25 and are also supported at paragraph 60.

Claim 57 has been canceled and its limitations moved to claims 43 (SEQ ID NO. 2) and 66 (SEQ ID NO. 4).

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New claim 60 is similar to claim 25 (SEQ ID NO. 2), except that it recites sequence identity to SEQ ID NO. 4. The limitations of this claim are supported by paragraphs 53, 54 and 56; the screening assays in paragraphs 78 and 80; knowledge and skill in the art; example 14 of the synopsis of application of the written description guidelines.

New claim 61 recites sequence identity to SEQ ID NO. 4, and is similar to claim 27 (SEQ ID NO:2). This claim is also supported in the specification as described in claim 27.

New claim 62 is like claim 38, except that it focuses on deletions from either or both ends of SEQ ID NO. 4.

New claim 63 is like claim 39, except that it focuses on deletions from either or both ends of SEQ ID NO: 4.

New claim 64 is like claim 40, except that it focuses on deletions from either or both ends of SEQ ID NO: 4.

New claim 65 is like claim 41, except that it focuses on deletions from either or both ends of SEQ ID NO: 4.

New claim 66 is like claim 43 except that it focuses on modifications of SEQ ID NO. 4. Support is at paragraphs 53, 54 and 56; the screening assays in paragraphs 78 and 80; knowledge and skill in the art; example 14 of the synopsis of application of the written description guidelines.

New claim 67, which recites sequence identity to SEQ ID NO. 4, is otherwise similar to claim 45 (SEQ ID NO. 2). There is support for this claim in paragraphs 54, 56 and 60 and paragraphs 78 and 80.

New claim 68, which recites sequence identity to SEQ ID NO. 4, is similar to claim 46 (SEQ ID NO:2). There is support in paragraphs 54, 56 and 60 and paragraphs 78 and 80.

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Other amendments to the claims not specifically discussed above have been made to improve claim form or to ensure coverage of embodiments to which Applicants are entitled. Each of the claims as they presently stand amended are believed to fully comply with 35 U.S.C. § 112 and distinguish over the cited reference for at least the same reasons as discussed in the Response to the July 16, 2003 Office Action, which is incorporated herein by reference.

### Conclusion

Applicants may have at times referred to claim limitations in shorthand fashion, or may have focused on a particular claim element. This discussion should not be interpreted to mean that the other limitations can be ignored or dismissed. The claims must be viewed as a whole, and each limitation of the claims must be considered when determining the patentability of the claims. Moreover, it should be understood that there may be other distinctions between the claims and the prior art, which have yet to be raised, but which may be raised in the future.

Consideration of the foregoing amendments and remarks, reconsideration of the application and withdrawal of the rejections and objections is respectfully requested by Applicants. No new matter is introduced by way of the amendments. If any item in the outstanding Office Action has been overlooked or is deemed to be incompletely addressed, Applicants respectfully request the opportunity to respond. Applicants believe that no extension of time is necessary for this paper to be deemed timely filed. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefor. If any fee is due as a result of the filing of this paper please appropriately charge such fee to Deposit Account Number 03-2769 of Conley Rose, P.C., Houston, Texas.

Respectfully submitted,



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AGENT FOR APPLICANT